General

Guideline Title

Screening for lipid disorders in children and adolescents: U.S. Preventive Services Task Force recommendation statement.

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for lipid disorders in children and adolescents: U.S. Preventive Services Task Force recommendation statement. JAMA. 2016 Aug 9;316(6):625-33. [33 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: US Preventive Services Task Force. Screening for lipid disorders in children: US Preventive Services Task Force recommendation statement. Pediatrics. 2007 Jul;120(1):e215-9.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for lipid disorders in children and adolescents 20 years or younger (I statement).

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to asymptomatic children and adolescents 20 years or younger without a known diagnosis of a lipid disorder.

Suggestions for Practice Regarding the I Statement

Potential Preventable Burden

Heterozygous familial hypercholesterolemia is an autosomal dominant disorder caused primarily by mutations in the low-density lipoprotein (LDL) receptor (LDLR) gene (NCBI Entrez Gene 3949) that causes severe elevations in levels of LDL cholesterol (LDL-C), resulting in early

atherosclerotic lesions. Children with familial hypercholesterolemia can have total cholesterol (TC) and LDL-C levels 2 to 3 times higher than those of unaffected children. Familial hypercholesterolemia is generally asymptomatic in childhood and adolescence and is rarely associated with cardiovascular events in the first 2 decades of life. The burden of familial hypercholesterolemia is attributable to premature cardiovascular events in adulthood resulting from long-term exposure to elevated serum cholesterol levels and atherosclerosis.

Studies conducted before statin use became common suggest that familial hypercholesterolemia is associated with a cumulative incidence of ischemic heart disease in 1 of 6 men and 1 of 10 women by age 40 years. By age 50 years, 25% of women and 50% of men with untreated familial hypercholesterolemia will experience clinical cardiovascular disease. Coronary artery disease occurs in 50% of men by age 50 years and 30% of women by age 60 years. Mortality from coronary artery disease is greater in adults younger than 60 years with familial hypercholesterolemia. Among adults surviving to age 60 years, the risk of coronary heart disease approaches that of the general population.

Multifactorial dyslipidemia is defined by elevated levels of LDL-C (≥130 mg/dL) or TC (≥200 mg/dL) that are not attributable to familial hypercholesterolemia. Several longitudinal studies have documented an association between childhood lipid levels in this range and measures of atherosclerosis in adulthood. Studies show that tracking lipid levels from childhood and adolescence to adulthood cannot predict which individuals will have elevated LDL-C or TC as adults. In addition, the association between multifactorial dyslipidemia in childhood and adolescence and clinical cardiovascular disease in adulthood is unknown.

Potential Harms

Most children with elevated lipid levels of a multifactorial origin will not progress to a clinically important lipid disorder or develop premature cardiovascular disease and are therefore subject to overdiagnosis. Screening could result in the labeling of children with a "nondisease," parental or child anxiety, or unnecessary or harmful testing and treatment. The adverse effects of long-term use of lipid lowering pharmacotherapy and lifestyle modification (including diet and physical activity) have not been adequately studied.

Current Practice

Generally, screening rates for dyslipidemia in children and adolescents seen in primary care have been low. According to the National Ambulatory Medical Care Survey, 2.5% of well-child visits included lipid testing in 1995, and 3.2% included it in 2010. Claims data from health insurance plans report rare use of lipid-lowering pharmacotherapy in 8- to 20-year-olds. Among more than 13 million children, 665 children initiated lipid-lowering pharmacotherapy between 2005 and 2010, for an overall incidence rate of 2.6 prescriptions per 100,000 person-years (95% confidence interval [CI], 0.1 to 2.7).

Screening Tests

Normal lipid level values for children and adolescents are currently defined by population distributions of lipid levels from the Lipid Research Clinics Prevalence Study, which was conducted in the 1970s. In 1992, the National Cholesterol Education Program (NCEP) proposed fixed threshold values to define dyslipidemia in children (TC ≥200 mg/dL, LDL-C ≥130 mg/dL, or both). These values are slightly lower than the 95th percentile observed in the Lipid Research Clinics Prevalence Study for both boys and girls at nearly all ages, although there are some age-related variations in adolescence.

Cholesterol levels vary by sex and age throughout childhood. Total cholesterol levels increase from birth, stabilize at approximately age 2 years, peak before puberty, and then decline slightly during adolescence. The accepted cut off values for elevated LDL-C and TC may overidentify or underidentify children and adolescents, depending on age and sex. Abnormal lipid levels in youth are based on population distributions, not associations with health outcomes. It is unclear to what degree elevated lipid levels in children and adolescents 20 years or younger are associated with future disease risk.

Elevated lipid levels track modestly into adulthood, making it difficult to predict which children and adolescents will continue to have elevated cholesterol levels as adults. Longitudinal studies suggest that elevated LDL-C levels in adolescence predict elevated LDL-C 15 to 20 years later, with a positive predictive value of 32.9% to 37.3% and lower predictive values among younger children.

Levels of TC may be measured with fasting or nonfasting serum testing. Serum (or plasma) TC and high-density lipoprotein (HDL-C) levels do not change appreciably according to a fasting or nonfasting state. Serum LDL-C levels may be calculated using the Friedewald formula (LDL-C = TC − [triglycerides/5] − HDL-C). Because accurate calculation depends on triglyceride levels, serum testing requires a fasting state. Direct measurement of LDL-C does not require fasting and is preferred when triglyceride levels are greater than 400 mg/dL. Recent guidelines on screening for dyslipidemia in children recommend measuring either LDL-C or non–HDL-C levels.

Screening strategies for dyslipidemia in clinical practice include selective or universal screening. Selective screening is based on family history of dyslipidemia or premature cardiovascular disease. Universal screening is based only on age. Cascade screening is a common screening strategy for familial hypercholesterolemia in other countries. Cascade screening involves case-finding among relatives of patients with confirmed familial

hypercholesterolemia and testing for genetic variants identified in the first affected relative (i.e., the proband). However, the U.S. health system does not currently have the infrastructure to implement cascade screening.

There are no universally accepted criteria for the diagnosis of familial hypercholesterolemia. Studies of children and adolescents with familial hypercholesterolemia use several different diagnostic criteria. All of the criteria use a combination of elevated lipid levels, physical findings, family history, or genetic tests to establish the diagnosis.

Treatment of Dyslipidemia

Interventions for dyslipidemia include lifestyle modification (e.g., changes in diet and physical activity) and pharmacotherapy (e.g., statins, bile acid–sequestering agents, or cholesterol absorption inhibitors).

Statins, or 3-hydroxy-3-methyl-glutaryl coenzyme A reductase inhibitors, have been widely adopted for use in adults with hypercholesterolemia, because these drugs are effective at reducing cardiovascular events in high-risk adults. As a result of their efficacy in adults, statins are one of the first-line medications considered for use in children and adolescents with hypercholesterolemia.

The appropriate age at which to start statin use in children with familial hypercholesterolemia is subject to debate. Some experts recommend starting statin use at age 8 or 10 years; others, concerned with adverse effects, recommend initiating use at age 20 years. The long-term effects of statin use in children and adolescents are unknown.

Useful Resources

The USPSTF recommends that clinicians screen for obesity in children 6 years or older and offer them or refer them to a comprehensive, intensive behavioral intervention (B recommendation). The USPSTF found insufficient evidence on screening for primary hypertension in asymptomatic children and adolescents to prevent subsequent cardiovascular disease in childhood or adulthood (I statement). These recommendations are available on the USPSTF website (https://www.uspreventiveservicestaskforce.org/).

Definitions

What the USPSTF Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • Lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Lipid disorders

- Heterozygous familial hypercholesterolemia
- Multifactorial dyslipidemia

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Nutrition

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To update the 2007 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for lipid disorders in children, adolescents, and young adults

Target Population

Asymptomatic children and adolescents 20 years or younger without a known diagnosis of a lipid disorder

Interventions and Practices Considered

Screening for lipid disorders (heterozygous familial hypercholesterolemia and multifactorial dyslipidemia)

Major Outcomes Considered

Multifactorial Dyslipidemia

Screening Key Questions

- Key Question 1: Does screening for multifactorial dyslipidemia in asymptomatic children and adolescents delay or reduce the incidence of myocardial infarction (MI) or stroke in adulthood?
- Key Question 2: Does screening for multifactorial dyslipidemia in asymptomatic children and adolescents improve intermediate outcomes* (i.e., improve lipid concentrations or reverse or slow the progression of atherosclerosis) in childhood and adolescence?
- Key Question 3: What is the diagnostic yield of screening for multifactorial dyslipidemia in children and adolescents?
- Key Question 4: What are the harms of screening for multifactorial dyslipidemia in children and adolescents?

Treatment Key Questions

- Key Question 5: Does treatment of multifactorial dyslipidemia with lifestyle modifications and/or lipid-lowering medications in children and adolescents delay or reduce the incidence of adult MI and stroke events?
- Key Question 6: Does treatment of multifactorial dyslipidemia with lifestyle modifications and/or lipid-lowering medications in children and adolescents improve intermediate outcomes* (i.e., reduce lipid concentrations or reverse or slow the progression of atherosclerosis) in childhood and adolescence?
- Key Question 7: What are the harms of treatment of multifactorial dyslipidemia with lifestyle modifications and/or lipid-lowering medications in children and adolescents?

Outcomes Key Questions

- Key Question 8: What is the association between intermediate outcomes* in childhood and adolescence and future incidence of MI and stroke events in adults?

Familial Hypercholesterolemia

Screening Key Questions

- Key Question 1: Does screening for familial hypercholesterolemia (FH) in asymptomatic children and adolescents delay or reduce the incidence of MI or stroke in adulthood?
    a. Selective screening based on family history
    b. Universal screening
- Key Question 2: Does screening for FH in asymptomatic children and adolescents improve intermediate outcomes† (i.e., reduce lipid concentrations or reverse or slow the progression of atherosclerosis) in childhood and adolescence?
    a. Selective screening based on family history
    b. Universal screening
- Key Question 3: What is the diagnostic yield of appropriate screening tests for FH in children and adolescents?
    a. Selective screening based on family history
    b. Universal screening
- Key Question 4: What are the harms of screening for FH in children and adolescents?

Treatment Key Questions

- Key Question 5: Does treatment of FH with lifestyle modifications and/or lipid-lowering medications in children and adolescents delay or reduce the incidence of adult MI and stroke events?
- Key Question 6: Does treatment of FH with lifestyle modifications and/or lipid-lowering medications in children and adolescents improve intermediate outcomes† (i.e., reduce lipid concentrations or reverse or slow the progression of atherosclerosis) in childhood and adolescence?
- Key Question 7: What are the harms of treatment of FH with medications in children and adolescents?

Outcomes Key Questions

- Key Question 8: What is the association between intermediate outcomes† in childhood and adolescence and future incidence or timing of adult MI and stroke events?

*Intermediate outcomes include lipid levels (total, low-density lipoprotein, high-density lipoprotein, and non–high-density lipoprotein cholesterol; triglycerides) and atherosclerosis markers (carotid intima-media thickness, calcium score, pathological findings).

†Intermediate outcomes include lipid levels (total and low-density lipoprotein cholesterol) and atherosclerosis markers (carotid intima-media thickness, calcium score, pathological findings).

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Multifactorial Dyslipidemia

Data Sources and Searches

A literature search was conducted using several databases, including MEDLINE and PubMed, British Medical Journal (BMJ) Clinical Evidence, Canadian Agency for Drugs and Technologies in Health, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment (Centre for Reviews and Dissemination), Institute for Clinical Systems Improvement, Institute of Medicine, and National Institute for Health and Care Excellence. The search included studies published January 1, 2005, or later. The original search was conducted on February 12, 2014, and updated on June 13, 2014, December 16, 2014, and June 2, 2015. After June 2015, the researchers continued to conduct ongoing surveillance through article alerts and targeted searches of high-impact journals to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on April 9, 2016, and identified no new relevant studies. The search strategies are listed in the eMethods in the evidence review supplement.

All studies included in the previous USPSTF evidence report were reviewed along with the reference lists of several reports, including the 2011 National Heart, Lung, and Blood Institute expert panel report, publications from large cohort studies with longitudinal data, and studies included in other relevant systematic reviews and meta-analyses. Relevant articles were solicited from expert reviewers, and ClinicalTrials.gov was searched to identify relevant ongoing trials.

Study Selection

All study selection procedures used dual independent review. The title and abstracts were reviewed, followed by the full text of all potentially relevant citations, against the a priori inclusion and exclusion criteria for design, population, screening, intervention, outcomes, and setting. Discrepancies were resolved through discussion.

The screening population of interest was asymptomatic people aged 0 to 20 years. Eligible screening interventions were defined as a lipid panel (fasting or nonfasting lipid measurement, total cholesterol [TC] or low-density lipoprotein cholesterol [LDL-C] alone or in combination with high density lipoprotein cholesterol [HDL-C]) delivered in a universal or selective screening strategy. Although non–HDL-C was not among the included screening interventions, no studies were excluded that screened youth using non–HDL-C. Screening studies with modes not relevant to primary care practice were excluded.

The treatment population of interest was people with multifactorial dyslipidemia (ideally screen-detected) aged 0 to 20 years who were treated with lipid-lowering drugs or lifestyle interventions. All reported clinical and laboratory harms associated with interventions that had any evidence of treatment benefit were included.

Studies of efficacy or effectiveness were limited to fair- or good-quality randomized clinical trials that were conducted in countries with a United Nations Human Development Index greater than 0.9. Studies conducted in very high Human Development Index countries are more likely to be applicable to U.S. settings. Trials, cohort studies, and observational studies that reported clinical or laboratory harms were included; case series and case reports were excluded.

Familial Hypercholesterolemia

Data Sources and Searches

A literature search was conducted using several databases, including MEDLINE and PubMed, BMJ Clinical Evidence, Canadian Agency for Drugs and Technologies in Health, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment (Centre for Reviews and Dissemination), Institute for Clinical Systems Improvement, Institute of Medicine, and National Institute for Health and Care Excellence. The search strategies are listed in the eMethods in the evidence review supplement.

The search included studies published January 1, 2005, or later. The original search was on February 12, 2014, and was updated on June 13, 2014, December 16, 2014, and June 2, 2015. Since June 2015, the researchers continued to conduct ongoing surveillance through article alerts and targeted searches of high-impact journals to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on April 8, 2016.

All studies included in the previous USPSTF evidence report were reviewed, along with the reference lists of several reports, including the 2011 National Heart, Lung, and Blood Institute Expert Panel Report, publications from large cohort studies with longitudinal data, and studies included in relevant systematic reviews and meta-analyses. Relevant articles were solicited from expert reviewers and ClinicalTrials.gov was searched to identify relevant ongoing trials.

Study Selection

All study selection procedures used dual independent review. The titles and abstracts were reviewed, followed by the full text of all potentially relevant citations, against the a priori inclusion and exclusion criteria for design, population, screening, intervention, outcomes, and setting.

Discrepancies were resolved through discussion. For screening studies (Key Questions [KQs] 1-4), studies of asymptomatic children and adolescents aged 0 to 20 years at screening were included. Acceptable screening interventions were lipid panel (fasting or nonfasting lipid measurement, TC or LDL-C alone or in combination with high-density lipoprotein cholesterol [HDL-C]) delivered in a universal or selective screening strategy. Screening studies that focused on genetic screening alone or cascade screening (which involves case-finding among relatives of people with confirmed FH) were excluded because those screening approaches are not relevant to screening for FH in primary care. Screening studies of populations with known dyslipidemia, a diagnosis associated with secondary dyslipidemia, or a documented family history of FH were excluded. Only screening studies that reported the number of children with probable or definite FH were included.

For treatment studies (KQs 5-7), interventions using lipid-lowering drugs or lifestyle interventions were included, focusing on interventions targeting people aged 0 to 20 years who had a diagnosis of FH at the beginning of the intervention (ideally screen-detected). Any class of lipid-lowering drug was accepted, including, but not limited to, 3-hydroxy-3-methyl-glutaryl coenzyme A reductase inhibitors (statins) and bile acid–sequestering agents. Studies that focused on treating those with secondary dyslipidemia or monogenic dyslipidemia other than FH were excluded. Treatment studies focusing on apheresis and revascularization were excluded, as those treatments are reserved for persons with homozygous FH. All reported clinical and laboratory harms associated with lipid-lowering drugs were included.

Studies with mixed dyslipidemic populations were included when the outcome data for participants with FH were presented separately. Studies in which the researchers specifically identified participants with FH using any specified and accepted criteria were included. Studies of efficacy or effectiveness were limited to fair- to good-quality randomized clinical trials that were conducted in countries with a United Nations Human Development Index greater than 0.9. Studies conducted in very high Human Development Index countries are more likely to be applicable to U.S. settings. Included intervention trials had to compare an intervention against a usual care or control group.

Health outcomes (KQ1, KQ5, and KQ8) were defined as those experienced by the patient. Atherosclerosis (carotid intima-media thickness [CIMT], calcium score, or autopsy findings) and TC or LDL-C concentrations were considered to be intermediate outcomes (KQ2 and KQ6). Trials, cohort studies, and observational studies that reported clinical or laboratory harms were included; case series and case reports were excluded.

Number of Source Documents

Multifactorial Dyslipidemia

A total of 7137 unique abstracts and 537 full-text articles were reviewed (see eFigure in the systematic review supplement). Of these, 16 articles were included.

Articles included for Key Questions:

- Key Question 1: 0 articles
- Key Question 2: 0 articles
- Key Question 3: 8 articles (4 studies)
- Key Question 4: 0 articles
- Key Question 5: 0 articles
- Key Question 6: 5 articles (2 studies)
- Key Question 7: 5 articles (1 study)
- Key Question 8: 1 articles (1 study)

Familial Hypercholesterolemia

A total of 6753 unique abstracts and 375 full-text articles were reviewed (see eFigure in the systematic review supplement). Of these, 27 articles were included.

- Key Question 1: 0 articles
- Key Question 2: 0 articles
- Key Question 3: 2 articles (2 studies)
- Key Question 4: 0 articles
- Key Question 5: 0 articles
- Key Question 6: 13 articles (13 studies)
- Key Question 7: 24 articles (18 studies)
- Key Question 8: 0 articles

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Two reviewers independently critically appraised articles meeting inclusion criteria as good, fair, or poor in accordance with USPSTF guidance (see the eTable in the supplement of the evidence review [see the "Availability of Companion Documents" field]).

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Multifactorial Dyslipidemia

Data Extraction and Quality Assessment

Two reviewers independently critically appraised articles meeting inclusion criteria as good, fair, or poor in accordance with USPSTF guidance (see the eTable in the evidence review supplement). Poor-quality studies were those with important limitations that could invalidate study findings and were excluded from the review.

For all included articles, data were abstracted into evidence tables, including study characteristics, study design elements, test characteristics for screening studies, intermediate and adult health outcomes, and harms, including all relevant subgroups where available.

Data Synthesis and Analysis

Summary tables of study characteristics, population characteristics, intervention characteristics, and outcomes were created separately for each Key Question (KQ). For treatment studies, lipid concentrations were expressed as percent change or difference from baseline. Data were not combined across treatment studies. No KQs had a sufficient number of included studies to permit meta-analysis.

Familial Hypercholesterolemia

Data Extraction and Quality Assessment

Two reviewers independently critically appraised articles meeting inclusion criteria as good, fair, or poor in accordance with USPSTF guidance (see eTable 4 in the evidence review supplement). Topic-specific quality criteria were designed with the assistance of clinical experts. Studies were rated as good, fair, or poor quality in accordance with USPSTF procedures. In general, a good-quality study met all quality criteria. A fair-quality study failed to meet at least 1 criterion but had no known issue that would invalidate its results. Poor-quality studies were those with important limitations that could invalidate study findings and were excluded from this review.

One reviewer extracted data from all included fair and good studies into a standard evidence table. A second reviewer checked the data for accuracy. The reviewers abstracted study characteristics, study design elements, randomized trial characteristics, outcomes for screening studies, intermediate outcomes and health outcomes, and harms.

Data Synthesis and Analysis

Data were qualitatively summarized in the evidence tables with respect to each KQ. For KQ6, the 6 studies were summarized in a plot of mean differences across statins by percent change from baseline of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C) concentrations. When trials reported standard errors or confidence intervals for the primary outcome, the

reported results were used to compute standard deviations. For 1 trial with 3 groups randomly assigned to different doses of a statin, weighted means and standard deviations were used to combine reported results into a single intervention effect for the study. Variability in drug, dosage, and intended duration of treatment precluded pooling data across studies.

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

U.S. Preventive Services Task Force Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A*, *B*, *C*, *D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the USPSTF's assessment of the overall body

of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].

I Statements

For I statements, the USPSTF has a plan to commission its Evidence-based Practice Centers (EPCs) to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205. www.annals.org .

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • Lack of information on important health outcomes

Level of Certainty	More information may allow an estimation of effects on health outcomes. **Description**

Cost Analysis

The U.S. Preventive Services Task Force (USPSTF) does not consider the costs of providing a service in this assessment.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review

Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send the draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from December 22, 2015, to January 25, 2016. The USPSTF reviewed all comments received. A few comments agreed with the insufficiency of the evidence; several comments disagreed with the recommendation. A few comments provided citations for related articles, and the USPSTF reviewed these for relevance to the current recommendation. The USPSTF added language to emphasize the burden of familial hypercholesterolemia and to clarify its diagnosis. The USPSTF also added language on the feasibility of research to the section on Research Needs and Gaps (see the original guideline document).

Comparison with Guidelines from Other Groups

Recommendations for screening from the following groups were discussed: the National Heart, Lung, and Blood Institute's Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents, the American Academy of Pediatrics' Bright Futures, American Academy of Family Physicians, and the UK National Screening Committee.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Benefits of Early Detection and Treatment

The U.S. Preventive Services Task Force (USPSTF) found inadequate direct evidence on the benefits of screening for familial hypercholesterolemia or multifactorial dyslipidemia.

Familial Hypercholesterolemia

The USPSTF found adequate evidence from short-term trials (≤2 years) that pharmacotherapy interventions result in substantial reductions in levels of low-density lipoprotein cholesterol (LDL-C) and total cholesterol (TC) in children with familial hypercholesterolemia. One short-term pharmacotherapy trial reported a reduction in carotid intima-media thickness. The USPSTF found inadequate evidence to address whether treatment with short-term pharmacotherapy leads directly to a reduced incidence of premature cardiovascular disease (e.g., myocardial infarction or stroke). The USPSTF found inadequate evidence on the association between changes in intermediate lipid outcomes or noninvasive measures of atherosclerosis in children and adolescents and incidence of or mortality from relevant adult health outcomes.

Multifactorial Dyslipidemia

The USPSTF found inadequate evidence on the benefits of lifestyle modification or pharmacotherapy interventions in children and adolescents with multifactorial dyslipidemia to improve intermediate lipid outcomes or atherosclerosis markers or to reduce incidence of premature cardiovascular disease.

Potential Harms

Harms of Early Detection and Treatment

The U.S. Preventive Services Task Force (USPSTF) found inadequate evidence to assess the harms of screening for familial hypercholesterolemia or multifactorial dyslipidemia. The USPSTF found inadequate evidence to assess the long-term harms of treatment of familial hypercholesterolemia in children or adolescents. Long-term evidence on the treatment of familial hypercholesterolemia was limited to 1 study of statins. Short-term statin use was generally well tolerated in children and adolescents with familial hypercholesterolemia, with transient adverse effects (such as elevated liver enzyme levels). Treatment with bile acid–sequestering agents was commonly associated with gastrointestinal symptoms and poor palatability. The USPSTF also found inadequate evidence to assess the harms of treatment of multifactorial dyslipidemia in children or adolescents. One trial of a low-fat, low-cholesterol dietary intervention in children with multifactorial dyslipidemia showed no harms.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without obvious related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools

for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for lipid disorders in children and adolescents: U.S. Preventive Services Task Force recommendation statement. JAMA. 2016 Aug 9;316(6):625-33. [33 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Aug 9

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services or its agencies.

Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality (AHRQ) support the operations of the USPSTF.

Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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*Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to https://www.uspreventiveservicestaskforce.org/Page/Name/our-members.

Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Conflict of Interest Disclosures

All authors have completed and submitted the International Committee of Medical Journal Editors (ICMJE) Form for Disclosure of Potential Conflicts of Interest. Dr. Bibbins-Domingo reported having consulted for the Institute for Clinical and Economic Review on the cost-effectiveness of a new class of lipid-lowering drugs. No other authors reported disclosures. Authors followed the policy regarding conflicts of interest described at https://www.uspreventiveservicestaskforce.org/Page/Name/conflict-of-interest-disclosures. All members of the USPSTF receive travel reimbursement and an honorarium for participating in USPSTF meetings.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: US Preventive Services Task Force. Screening for lipid disorders in children: US Preventive Services Task Force recommendation statement. Pediatrics. 2007 Jul;120(1):e215-9.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Journal of the American Medical Association (JAMA) Web site.

Availability of Companion Documents

The following are available:

Evidence Reviews:

- Lozano P, Henrikson NB, Morrison CC, Dunn J, Nguyen M, Blasi P, Whitlock E. Lipid screening in childhood for detection of multifactorial dyslipidemia: evidence report and systematic review for the U.S. Preventive Services Task Force. JAMA. 2016 Aug 9;316(6):634-44.
- Lozano P, Henrikson NB, Morrison CC, Dunn J, Nguyen M, Blasi P, Whitlock E. Lipid screening in childhood for detection of multifactorial dyslipidemia: a systematic evidence review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 140. AHRQ Publication No. 14-05204-EF-1. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016 Aug. 117 p.
- Lozano P, Henrikson NB, Dunn J, Morrison CC, Nguyen M, Blasi P, Anderson ML, Whitlock E. Lipid screening in childhood and adolescence for detection of familial hypercholesterolemia: evidence report and systematic review for the U.S. Preventive Services Task Force. JAMA. 2016 Aug 9;316(6):645-55.
- Lozano P, Henrikson NB, Dunn J, Morrison CC, Nguyen M, Blasi P, Anderson ML, Whitlock E. Lipid screening in childhood and adolescence for detection of familial hypercholesterolemia: a systematic evidence review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 141. AHRQ Publication No. 14-05204-EF-2. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016 Aug. 135 p.

Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med 2007;147:123-7.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med 2007;147:117-22.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med 2007;147:871-5.

- Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205.

Available from the USPSTF Web site.

The following are also available:

- Screening for lipid disorders in children and adolescents: clinical summary. Rockville (MD): U.S. Preventive Services Task Force. 2016 Aug. 1 p. Available from the USPSTF Web site.
- A continuing medical education (CME) activity is available free with registration from the Journal of the American Medical Association (JAMA) Web site.

The Electronic Preventive Services Selector (ePSS) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

Patient Resources

The following is available:

- Screening for lipid disorders in children and adolescents: JAMA patient page. JAMA. 2016;316(6):678. Available from the Journal of the American Medical Association (JAMA) Web site.

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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